

MAY 14 2007

Application No.: 08/444,791

Docket No.: 01017/40451C

(3) directing the Examiner to withdraw finality of the Office Action mailed March 12, 2007 as premature.

III. Statement of Reasons That Requested Relief Should Be Granted

A. The Election Requirements Were Improper

1. The election requirement between p55 and p75 TNFR species was waived in the two restriction/election requirements after Applicants' Rule 129 submission

The Examiner waived the election requirement between the p55 and p75 TNFR species by (1) failing to re-state or refer to the requirement in any of the six official communications, including two restriction/election requirements, mailed subsequent to Applicants' Rule 129 submission of June 17, 2003, and (2) stating in the January 25, 2006 communication that a p75 TNFR sequence would be the subject of "prosecution on the merits." It was improper for the Examiner to raise the species election for the first time in the September 26, 2006 office action, more than three years after Applicants' Rule 129 submission, and after Applicants explicitly reminded the Examiner that no election had been required between p55 and p75.

According to MPEP § 707.07(e):

The examiner should note in every letter all the requirements outstanding against the application. Every point in the prior action of an examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the requirement. [emphasis added]

Even though Applicants reminded Examiner in remarks filed December 9, 2004²² that there had been no requirement for election between p55 or p75 TNFR species, the Examiner *never referred to any election requirement between p55 and p75 species* during any of the three in-person interviews conducted since November 2004 or in either of the restriction/election requirements issued after Applicants Rule 129 submission on June 17, 2003. This failure to repeat or refer to the election requirement between p55 and p75 species, despite repeating or referring to other prior restriction/election requirements, was an *implied waiver of the requirement*.

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Applicants reasonably believed that after their filing of a Rule 129 submission (June 17, 2003), the Examiner had exercised his discretion to examine both the p55 and p75 species. The last restriction requirement (June 1, 2001) mailed prior to the Rule 129 submission had required election between the TNFR species p55 and p75, and between immunoglobulin species IgG1 and IgG3. However, the new restriction requirement mailed September 23, 2003, after the Rule 129 response, *completely omitted the election requirement between p55 and p75 species despite repeating other* prior restriction and election requirements, *i.e.*, reiterating the election between IgG1 or IgG3, and reiterating a restriction between DNA, protein, and other groups originally applied in the parent application. This September 23, 2003 communication was thus an implied waiver of the p55/p75 election requirement.

During the past two and a half years, Applicants have initiated a series of in-person interviews to obtain guidance from the Examiner and to attempt to streamline prosecution of this application. Applicants specifically discussed claims directed to the p75 species in their in-person interview on November 18, 2004. The only restriction/election issue raised by the Examiner during the interview was whether the Examiner would permit a switch from polynucleotide claims to protein claims.²³ Applicants also specifically stated in their remarks of December 9, 2004 that there was no election required between p55 or p75. Despite this, the Examiner *failed to mention any concern regarding an election of p55 or p75 species* in the subsequent in-person interview of September 20, 2005, the further in-person interview of June 22, 2006, or any of the numerous official communications issued between June 17, 2003 and September 26, 2006. This prosecution history should be viewed as an implied waiver of the p55/p75 election requirement.

Moreover, by requiring Applicants to elect one of three recited p75 TNFR sequences for search and examination in the January 25, 2006 election requirement (requiring election of SEQ ID NO: 12, 8, or 10 which each are part of the p75 TNFR sequence), the Examiner stated that such sequence would be the subject of "prosecution on the merits," thus indicating the sequence would be searched and examined. Applicants' interpretation is consistent with the Examiner's statements during the October 24, 2006 telephonic interview that he intended to conduct another search. The January 25, 2006 election requirement also

²² See page 13 of Applicants' amendment and response filed December 9, 2004 in the present application.

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failed to refer to any election requirement between the p55 or p75 species. This office action did not require such an election, nor did it mention that the election of the p55 species was still in effect. Even absent the other circumstances described above, this communication alone would be an explicit waiver of the election requirement.

The Examiner could and should have given Applicants notice in an office action immediately subsequent to their Rule 129 submission on June 17, 2003 of his position that Applicants had constructively elected the p55 species on August 9, 2001. More than three years have passed since the Rule 129 submission, and numerous papers have been issued by the Examiner in this time, including, as described above, two restriction requirements. Thus, the Examiner has needlessly delayed prosecution by asking the Applicants to elect species, although he now maintains that they previously elected a species, and has clearly waived the prior requirement by repeatedly failing to refer to it.

Applicants reasonably believed that the p75 TNFR species was currently under examination and relied on that belief by preparing and filing arguments and other submissions based on p75 TNFR species. A court may set aside an agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C § 706, the Administrative Procedure Act. The Patent Office's actions in this case qualify as improper even under this standard.

For all of these reasons, Applicants respectfully submit that it was improper to raise an election requirement between the p55 and p75 species in the September 26, 2006 office action, more than three years after Applicants' filing of a Rule 129 submission, and that the election of species requirement should be withdrawn.

2. It is not a serious burden to examine the p55 and p75 species together because the genus is small and the rejections would have a similar basis

Although the p55 and p75 species are patentably distinct, the Office has not established that it would be a "serious burden" to examine all species in the Markush group pursuant to MPEP § 803.02, which states:

²³ See page 14 of Applicants' amendment and response filed December 9, 2004 in the present application.

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If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the *examiner must examine all the members of the Markush group* in the claim on the merits, *even though they may be directed to independent and distinct inventions*. [emphasis added]

The number of species is few, and Applicants believe that examination of all claims would not be burdensome because the Examiner would cite the same or similar art for the p75 species as for the p55 species. The basis of the pending rejection of the claims relating to polynucleotides encoding p55 TNFR fusions is a combination of Schall et al., a reference that purportedly discloses the p55 TNFR sequence, with Capon et al., a reference that purportedly discloses hybrid immunoglobulin fusions. During the November 18, 2004 in-person interview, the Examiner indicated that his rejection of p75 TNFR fusion claims would have a similar basis. See page 17 of Applicants' amendment and remarks filed December 9, 2004, which states "It was the Examiner's position during the interview that Capon, if combined with other art teaching the TNF receptor sequence, would render obvious claims to TNF receptor-Ig fusion proteins."

It is also apparent from a comparison of Applicants' previous arguments with respect to p55 and p75 TNFR fusion proteins that Applicants' arguments would overlap such that consideration of the arguments together would not be a serious burden. With respect to p55 TNFR fusion protein claims in the '279 patent, Applicants successfully argued, *inter alia*, that new and unexpected results were achieved by the claimed p55 TNFR fusion protein.²⁴ Applicants made similar arguments in the present application with respect to claims relating to p75 TNFR fusion proteins.²⁵

For all these reasons, the examination of the p55 and p75 species together may be made without serious burden, and an election requirement between the two species is improper.

²⁴ See pages 20-23 of the supplemental amendment and response filed January 19, 1996 in the '279 patent.

²⁵ See pages 16-18 of Applicants' amendment and response filed December 9, 2004 in the present application.

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3. The Examiner waived the prior election of IgG3 species in the restriction/election requirements after Applicants' Rule 129 submission

The Examiner waived the prior election of IgG3 species by re-stating the election requirement between IgG1 and IgG3 species in the September 23, 2003 Office Action²⁶. Applicants' elected IgG1 species in their paper filed March 22, 2004²⁷ and re-affirmed this election in their paper filed December 9, 2004.²⁸ After having waived the prior election and instituted a new election of species requirement, the Examiner cannot now turn back the clock and return to an election made *over six years ago*.

None of the six official communications since the Rule 129 submission, including the two restriction/election requirements mailed since then, refer to a constructive election of IgG3 species. The *first* time the constructive election of IgG3 species was mentioned was in the March 12, 2007 Office Action, after Applicants had explicitly informed the Examiner in two papers that they were electing IgG1 in response to the new election requirement. The September 23, 2003 Office Action was thus an explicit waiver of Applicants' prior election, and was completely consistent with the Examiner's discretion to allow a switch of invention or election groups after filing of a Rule 129 submission.

It was improper to ignore the explicit waiver of the prior election of IgG3 species. The re-instatement of an obsolete species election made six years ago is improper even under the standard for setting aside an agency action in court, i.e. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C § 706, the Administrative Procedure Act.

B. Finality Was Premature

1. A final first office action is not appropriate because the Rule 129 submission was filed before June 8, 2005

Under MPEP § 706.07(g), after a submission under Rule 129 filed prior to June 8, 2005, "the next Office action on the merits *may be made final only under the*

²⁶ See page 3 of September 23, 2003 Office Action in the present application.

²⁷ See page 2 of Applicants' amendment and response filed March 22, 2004 in the present application.

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conditions for making a first action in a continuing application final set forth in MPEP § 706.07(b). [emphasis added]” In contrast, after a Rule 129 submission filed on or after June 8, 2005, the next Office Action “will be made final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an IDS filed during the period set forth in 37 CFR 1.98(c) with the fee set forth in 37 CFR 1.17(p).” MPEP § 706.07(g).

Although numerous papers have passed between applicants and the examiner in the instant case since the Rule 129 submission, it is the date of the Rule 129 submission itself that is determinative according to the above-cited guidance. Since the Rule 129 submission in question was filed on June 17, 2003, the pre-June 8, 2005 standards apply, and a final first action was not appropriate.

2. Applicants are entitled to a full and fair hearing

Under MPEP § 706.76,

Before final rejection is in order a clear issue should be developed between the examiner and applicant. . . . The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal. [emphasis added]

Applicants did not have an adequate opportunity to respond with arguments regarding the p55 TNFR species because the final first Office Action was the first confirmation in *over three years* that the p55 species was the sole species under examination. The Examiner has an obligation to advance prosecution as well, rather than prematurely apply finality. Applicants’ remarks indicated that they believed the pending claims were patentable for the same reasons that parallel claims were deemed patentable in the parent ‘279 patent.²⁸ The finality of the Office Action is improper because it prevents meaningful advancement of prosecution and prematurely precludes opportunities to clarify issues with respect to patentability.

²⁸ See page 14 of Applicants’ amendment and response filed December 9, 2004 in the present application.

²⁹ See page 18 of Applicants’ amendment and response filed November 22, 2006 in the present application.

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The final first Office Action was the first time since the Rule 129 submission (June 17, 2003) that the Examiner confirmed that solely the p55 TNFR species would be examined. During that time period, in 2004, new counsel became responsible for prosecuting the application. New counsel did not have a fair opportunity to consider and supply arguments or evidence regarding the p55 TNFR species. In fact, claims relating to the p55 species had not even been present in the application for two years, since 2004. They were added for the first time in an amendment filed November 22, 2006 at the Examiner's request.

Applicants reasonably believed, based on the multiple office actions regarding restriction/election and the in-person interviews, that a new search would be done and that prosecution would be reopened after filing of the Rule 129 submission. During the interview, the Examiner suggested that Applicants add a few claims encompassing the p55 species and invited Applicants to explain their rationale for examining the p75 species.³⁰ The Examiner confirmed during the October 24, 2006 telephonic interview that a new search would be conducted.³¹ In view of the change in counsel, and the fact that the p55 claims had only recently been added, closing prosecution prematurely prevented Applicants from having an adequate opportunity to respond.

Applicants noted twice that the claims paralleled previously issued claims.³² Applicants' remarks in the November 22, 2006 amendment indicated that they believed the claims in the present application were patentable for the same reasons that the parent claims were patentable. The claims of the '279 patent were originally rejected, but were eventually allowed, over the exact same art applied to the present claims. The Examiner would have known that the rejections were identical because he would have reviewed the record of the parent application in accordance with MPEP §§ 707.05, 719.05 and 904.³³

³⁰ See page 15 of Applicants' amendment and response filed November 22, 2006 in the present application.

³¹ See page 17 of Applicants' amendment and response filed November 22, 2006 in the present application.

³² See page 14 of Applicants' amendment and response filed December 9, 2004 and page 18 of Applicants' amendment and response filed November 22, 2006 in the present application.

³³ MPEP §§707.05 and 904 state that: "the parent applications should be reviewed by the examiner for pertinent prior art." MPEP 707.05 also states that copies of references supplied in the parent case need not be provided again to applicant. MPEP 719.05 includes the following among its instructions for searching an application: "(E) A review of art cited in a parent application or an original patent, as required for all continuation and continuation-in-part applications, divisional applications, reissue applications and reexamination proceedings, or a review of art cited in related applications. Record the application number of a parent application that is still pending or abandoned, followed by 'refs. Checked' or 'refs. ck'ed.' If for any reason not all of the references have been checked because they are not available or clearly not relevant, such exceptions should be noted."

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MPEP §706 states that: "The standards of patentability applied in the examination of claims must be the same throughout the Office." Under MPEP §706.04, "[f]ull faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art."³⁴ The Examiner has cited no new art that would explain why the present claims are rejected while parallel claims were deemed patentable in the '279 patent. The March 12, 2007 Office Action failed to clarify why the Examiner came to a different conclusion regarding patentability from the Examiner in the '279 patent, in a way that would advance prosecution and clarify issues regarding patentability. Thus this Office Action was prematurely and improperly made final.

MPEP §706 makes clear that the Examiner's actions should be as constructive as possible:

When an application discloses patentable subject matter and it is apparent from the claims and the applicant's arguments that the claims are intended to be directed to such patentable subject matter, but the claims in their present form cannot be allowed because of defects in form or omission of a limitation, the examiner should not stop with a bare objection or rejection of the claims. *The examiner's action should be constructive in nature and when possible should offer a definite suggestion for correction.*

III. PATENTABLE SUBJECT MATTER DISCLOSED BUT NOT CLAIMED

If the examiner is satisfied after the search has been completed that patentable subject matter has been disclosed and the record indicates that the applicant intends to claim such subject matter, *he or she may note in the Office action that certain aspects or features of the patentable invention have not been claimed and that if properly claimed such claims may be given favorable consideration.* [emphasis added]

The finality of the March 12, 2007 Office Action was premature because it merely delays prosecution and precludes opportunities to refine issues with respect to patentability. Finality should be withdrawn to allow Applicants an opportunity for a full and fair hearing.

³⁴ MPEP § 706.04 states: "Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach . . . Because it is unusual to reject a previously allowed claim, the examiner should point out in his or her office action that the claim now being rejected was previously allowed by using Form Paragraph 7.50 [a form paragraph indicating that the rejection is based on newly cited references]."

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3. Applicants have been making a bona fide effort to advance prosecution

Issuance of a final first Office Action was premature because Applicants have been making a bona fide effort to advance prosecution, as evidenced by the June 5, 2003 in-person interview by prior counsel, subsequent three in-person interviews by undersigned counsel, and the submission of supplemental arguments and evidence prior to a first office action on the merits. The Examiner dismissed Applicants' extensive efforts to advance prosecution with a single sentence: "Regarding applicants various arguments related to nucleic acids encoding the 75 kD TNF receptor, said invention is not under consideration."³⁵

In other analogous circumstances, where applicants have made a bona fide effort to reply but the reply appears incomplete, Patent Office practice is to notify applicants, by telephone if possible, and to provide a new one-month period for completing the reply. See, e.g., MPEP § 714.03.³⁶ In this case, the Examiner could have telephoned the Applicants to confirm that he was examining the p55 TNFR species and that Applicants' supplemental arguments and evidence would not be considered, thus allowing Applicants the opportunity to submit additional arguments if desired.

The origin of the "first action final rejection" (FAFR) practice was to discourage intentional delay by applicants:

In accordance with statutory intent, one objective of Office practice has been to reduce delays in the prosecution of applications. FAFR practice served that objective by forcing an applicant to draft claims in the renewal in view of the prosecution history in the original and make a bona fide effort to define issues for appeal or allowance. *In re Bogese*, 1991 Commr. Pat. Lexis 28, *12 (Comm'r Pat. October 4, 1991)

This rationale behind FAFR practice does not apply to this case, where Applicants have made substantial and bona fide efforts to reduce delay in prosecution by attempting to better define and pre-emptively address patentability issues. Closing prosecution prematurely by issuing a final office action, without allowing new counsel an opportunity to present arguments, was contrary to the rationale behind FAFR practice and

³⁵ See page 8 of March 12, 2007 Office Action in the present application.

³⁶ Under MPEP § 714.03, "Where the amendment is bona fide but contains a serious omission," the examiner should "notify applicant that the omission must be supplied within the time period for reply; or . . . issue an Office action setting a 1-month time period to complete the reply." The Examiner is directed to make such notification, "if possible, by telephone."

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guidance in the MPEP to advance prosecution in a constructive manner so as to clarify patentability issues.

4. Finality was improper because the rejections could not be made on the same grounds of record

A final first Office Action is appropriate in the instant case only if "all the claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application." MPEP § 706.07(b). The finality of the March 12, 2007 action was improper because the claims could not be rejected on the same grounds of record, since applicants had submitted new arguments concerning the written description rejections. For example, compare Applicants' argument with respect to written description on pages 4-5 of Applicants' January 14, 2003 response with the arguments on pages 9-19 of Applicants June 17, 2003 response. Applicants added citations to many different portions of the specification to support their argument that the written description requirement was satisfied.

As discussed above, the instant Rule 129 submission (since it was filed prior to June 8, 2005) is entitled to be treated like a continuing application for the purpose of determining whether a final office action is proper. Applicants submitted new arguments regarding written description in the response and Rule 129 submission dated June 17, 2003.³⁷ Thus, the claims could not be rejected on the grounds of record, and a final office action was therefore improper.

5. Finality was improper because the species election requirement was improper

Applicants submit that a final first Office Action was improper because the species election requirement, which served as the basis for the Examiner to withdraw all claims other than those encompassing the p55 species, was improper. In the instant case, there were numerous claims, i.e., claims 125, 127-130, 132-138, 140-145, 147-149, 155-203,

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pending in the application which could not have been rejected on the grounds and art of record, but all were withdrawn from consideration pursuant to the improper species requirement discussed above. Thus, if, as Applicants have argued, the species requirement is improper and the pre-June 8, 2005 Rule 129 submission is entitled to be treated as a continuing application for purposes of determining the propriety of a final first Office Action, then the final first Office Action was also improper.

Alternatively, if the Office does not agree that the instant Rule 129 submission is entitled to the treatment accorded to a continuing application, a first action final was still improper because applicants were actively led to believe that the IgG1 and p75 species would be examined by issuance of two restriction requirements³⁸ subsequent to the Rule 129 submission. Therefore, it was inappropriate to issue a final first action based on the examination of a species other than that which applicants had elected.

C. The rules should be suspended or waived if necessary to allow Applicants to petition

If finality of a decision on an election requirement is required pursuant to 37 C.F.R. §1.144 in order for Applicants to petition the decision, Applicants respectfully request that either (1) such decision be considered final in light of the finality of the entire March 12, 2007 Office Action or (2) the rule be waived to allow Applicants to petition the decision.

It would be an injustice and a violation of due process if the Examiner's refusal to make the decision in the March 12, 2007 Office Action final rendered it impossible for Applicants to petition for review of that decision and the previous two restriction/election requirements issued since Applicants' Rule 129 submission on July 17, 2003.

Thus, justice requires that the rules be suspended or waived if necessary.

³⁷ See section I.C. above.

³⁸ The Office Actions dated September 23, 2003 and January 25, 2006.